



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: January 24, 2014

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary *Ben Brancel*
Steve Ingham, Division of Food Safety Administrator *Steve Ingham*

SUBJECT: ATCP 55-Meat and Meat Food Products; Hearing Draft Rule

PRESENTED BY: Steve Ingham

REQUESTED ACTION:

At the February 19, 2014 Board meeting, the department will ask the Board to authorize public hearings on a proposed rule to modify ch. ATCP 55, Meat and Meat Food Products. The proposed rule specifies corrective actions that state-licensed meat establishments must impose on certain livestock producers before the establishment operator accepts animals from the producer for slaughter. The required corrective actions apply to livestock producers who, on two or more occasions during a calendar year, submit animals testing positive for any illegal drug residue to be slaughtered at a state- or federally inspected meat establishment.

SUMMARY:

Background

Medications are important for maintaining healthy livestock. However, if not carefully managed, drug residues may remain in animals submitted for slaughter. Residues of medications in meat, particularly antibiotics and anti-inflammatory agents, can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The anti-inflammatory drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as is needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected by the United States Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS) to check the published Residue Repeat Violators list. The list identifies livestock producers whose animals have had two or more positive drug residue test results in the past year. Meat establishment operators are also expected to take appropriate measures before accepting animals from these producers. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture is jeopardized by the few

Agriculture generates \$59 billion for Wisconsin

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Wisconsin producers who repeatedly violate prohibitions against drug residues in livestock and meat products.

Rule Content

Currently ATCP 55 (Meat and meat food products) addresses the production of meat and meat food products starting with the submission of an animal for slaughter for human consumption and, by reference, adopts United States Department of Agriculture regulations prohibiting the slaughter of "downer" cattle (non-ambulatory) for human food or feed destined for bovine animals.

Current rules prohibit slaughter of a food animal for human consumption or submission of a food animal for slaughter if the person knows or has reason to know the animal is diseased or injured. The proposed rule will further prohibit someone from slaughtering or submitting for slaughter a food animal for human consumption if they know that the animal is adulterated. The rule then defines animals from producers included on the USDA Residue Repeat Violator List for use by Livestock Markets and Establishments as adulterated unless the producer provides written evidence that they have completed a course on proper administration of animal medications. The department will approve a course or courses which are acceptable. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian.

The proposed rule also revises ATCP 55.07, which requires persons who knows or has reason to know that he or she is submitting a diseased or injured animal for slaughter to sign and deliver a written statement to the person who will perform the slaughter. The proposed rule will revise the requirement that the written statement include a list of all drugs administered to the animal as treatments or feed within 30 days prior to the slaughter submission date. The rule will instead require that the statement certify that the withdrawal time following administration of all drugs as treatments or feed additives has complied with the manufacturer's recommendations. This revision acknowledges that some drugs may require a withdrawal time longer than 30 days.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

Federal meat and poultry inspection regulations require meat and poultry processors to adopt Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Establishment operators must develop a plan to monitor and document that each key step is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally-inspected establishments are required by 9 CFR 417.2 (a) (3) (v) to identify preventive measures for food safety hazards that could arise from drug residues. Drug residues include veterinary drugs, pesticides, and environmental contaminants.

One approach for minimizing drug residue risks is for abattoir operators to avoid accepting animals from sources that have had drug residue violations in the past. Since past performance is often the best indicator as to whether an animal may have a drug residue problem, federal establishment operators are expected, but not required, to consult the federal Residue Repeat

Violator List for use by Livestock Markets and Establishments before accepting animals for slaughter. This list is compiled as part of the National Residue Program (NRP) at FSIS, which has collected data on drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12 months under this sampling program are placed on the federal Residue Repeat Violator List.

State meat inspection programs operate under a cooperative agreement with the USDA-FSIS. Under this agreement, state meat inspection programs are required to adopt regulations that are "at least equal to" federal meat and poultry inspection regulations. In addition, Wisconsin is one of three states recently accepted into the Cooperative Interstate Shipment (CIS) program allowing certain selected meat establishments to ship their products in interstate commerce. States in the CIS program must adopt regulations that are the "same as" federal meat inspection regulations.

The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. It will enhance the effectiveness of these procedures by adding an additional educational corrective action that would be required of the producer by the abattoir operator well before federal regulatory action is needed.

Comparison with Rules in Adjacent States

Michigan currently does not operate a state meat and poultry inspection program and all meat slaughtered and processed in Michigan is federally-inspected by USDA. Illinois' state meat inspection program includes USDA's Federal-State Cooperative program (formerly known as the "Talmadge-Aiken" program). Under this program, state inspectors conduct federal inspections. Minnesota and Iowa operate state meat inspection programs. All processors of meat and meat products, whether operating under state meat-inspection programs or the USDA program, are expected to minimize the risk associated with drug residues and to consult the USDA's Residue Repeat Violator List for use by Livestock Markets and Establishments before purchasing animals for slaughter. The approach proposed in this rule revision is innovative and goes beyond requirements in neighboring states which operate state meat inspection programs. Although enforcement of the provisions in the proposed rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

Summary of Factual Data and Analytical Methodologies

Proposed rule changes were developed after careful analysis of federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. The department consulted with a large livestock medication and veterinary services company, and with the Wisconsin Veterinary Medical Association before developing the proposed rule. Both entities supported the intent of the proposed rule.

Effect on Small Business

This rule change is anticipated to have very little impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarians. There will be a slight short-term negative economic impact on livestock producers who must attend a course and improve documentation of animal medications as a result of the proposed rule. There will be a slight impact on the veterinarians of these few producers, because completion of the course will require involvement of the veterinarian. To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility rate payers.

Next Steps

If the Board authorizes public hearings on this rule, the department will refer a copy of the rule to the Legislative Council Rules Clearinghouse and publish a hearing notice in the Wisconsin Administrative Register. The department plans to hold hearings in Green Bay, Eau Claire, and Madison.

Following the public hearings, the department will evaluate all comments received at the hearings and prepare a final draft rule for the Board's consideration. If the Board approves a final draft rule, the department will transmit the final draft rule for the Governor's approval. After the Governor's approval, the final draft will be submitted for legislative committee review. If the Legislature has no objections to the rule, the Secretary will sign the final rulemaking order and transmit it for publication. The rule will take effect upon publication in the Wisconsin Administrative Register unless the final draft rule specifies a later effective date.

**PROPOSED ORDER
OF THE WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION
ADOPTING RULES**

- 1 The Wisconsin department of agriculture, trade and consumer protection hereby proposes the
2 following rule *to amend* ATCP 55.07(6) and (7)(f) and *to create* ATCP 55.07(6) (Note); *relating*
3 *to drug residues in animals for human food, and affecting small business.*

**Analysis Prepared by the Department
of Agriculture, Trade and Consumer Protection**

The Department of Agriculture, Trade and Consumer Protection (DATCP) proposes a rule revision for ch. ATCP 55, Wis. Adm. Code, specifying corrective actions that state-licensed meat establishments must impose on certain livestock producers before the establishment operator accepts animals from the producer for slaughter. The required corrective actions apply to livestock producers who, on two or more occasions during the past year, submit animals testing positive for any illegal drug residue to be slaughtered at a state or federally inspected meat establishment.

Statutes Interpreted

Statute Interpreted: s. 97.42, Stats.

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4), and 97.42 (4)Stats.

Explanation of Statutory Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The department has specific authority to promulgate rules related to compulsory inspection of animals, poultry and carcasses under s. 97.42 (4), Stats., which allows the department to establish rules related to the inspections before and after slaughter of all animals and poultry killed or dressed for human consumption at any establishment.

Related Statutes and Rules

Wisconsin's state meat and poultry inspection program is governed by ch. 97, Stats. (Food Regulation), including s. 97.42, Stats. (Compulsory inspection of animals, poultry and carcasses). Chapter ATCP 55 interprets and implements ch. 97, Stats., as it relates to Meat and Meat Food Products.

State meat and poultry inspection programs operate under a cooperative agreement with the USDA's Food Safety and Inspection Service (FSIS) to provide inspection services to small and very small meat establishments. State meat and poultry inspection programs were established by the Wholesome Meat Act of 1967 and the Wholesome Poultry Products Act of 1968, which amended the Federal Meat Inspection Act (FMIA) to create 21 U.S.C. 661 and the Poultry Products Inspection Act (PPIA) to create 21 U.S.C. 454. Section 11015 of Title XI of the Food, Conservation, and Energy Act of 2008 (the 2008 "Farm Bill"), enacted on June 18, 2008, amended FMIA and PPIA to establish a new voluntary program that will allow certain selected state-inspected meat establishments to sell their products in interstate commerce.

Title 9, Animal and Animal Products, of the Code of Federal Regulations (CFR) interprets and implements the federal FMIA and PPIA. Section 97.42 (4m), Stats., and ch. ATCP 55 adopt certain relevant sections of Title 9 that establish slaughter and processing standards for meat and meat products.

Plain Language Analysis

Medications are important for maintaining healthy livestock. However, if not carefully managed, drug residues may remain in animals submitted for slaughter. Residues of medications in meat, particularly antibiotics and anti-inflammatory agents, can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The anti-inflammatory drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as is needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected by USDA-FSIS to check the published Residue Repeat Violators list. The list identifies livestock producers whose animals have had two or more positive drug residue test results in the past year. Meat establishment operators are also expected to take appropriate measures before accepting animals from these producers. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture industry is jeopardized by the few Wisconsin producers who repeatedly violate prohibitions against drug residues in livestock and meat products.

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The proposed rule also revises ATCP 55.07, which requires a person who knows or has reason to know that he or she is submitting a diseased or injured animal for slaughter to sign and deliver a written statement to the person who will perform the slaughter. The proposed rule will revise the requirement that the written statement include a list of all drugs administered to the animal as treatments or feed within 30 days prior to the slaughter submission date. The rule will instead require that the statement certify that the withdrawal time following administration of all drugs as treatments or feed additives has complied with the manufacturer's recommendations. This revision acknowledges that some drugs may require a withdrawal time longer than 30 days.

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One approach for minimizing drug residue risks is for abattoir operators to avoid accepting animals from sources that have had drug residue violations in the past. Since past performance is often the best indicator as to whether an animal may have a drug residue problem, federal plants are expected to consult the federal Residue Repeat Violator List for use by Livestock Markets and Establishments before accepting animals for slaughter. This list is compiled as part of the National Residue Program (NRP) at FSIS, which has collected data on drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12 months under this sampling program are placed on the federal Residue Repeat Violator List.

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“at least equal to” federal meat and poultry inspection regulations. In addition, Wisconsin is one of three states recently accepted into the Cooperative Interstate Shipment (CIS) program allowing certain selected meat establishments to ship their products in interstate commerce. States in the CIS program must adopt regulations that are the “same as” federal meat inspection regulations.

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Effect on Small Business

This rule change is anticipated to have little impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarians. There will be a slight short-term negative economic impact on livestock producers who must attend a course and improve documentation of animal medications as a result of the proposed rule. There will be a slight impact on the veterinarians of

these few producers, because completion of the course will require involvement of the veterinarian. To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility rate payers.

DATCP Contact

Cindy Klug, Director
Bureau of Food Safety and Inspection
Department of Agriculture, Trade and Consumer Protection
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Madison, WI 53708-8911
Telephone: (608) 224-4729 E-Mail: Cindy.Klug@Wisconsin.gov

Where and When Comments May Be Submitted

Questions and comments related to this rule may be directed to:

Cindy Klug, Director
Bureau of Food Safety and Inspection
Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4711
E-Mail: Cindy.Klug@Wisconsin.gov

Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this rule is approved by the Board of Agriculture, Trade and Consumer Protection.

SECTION 1. ATCP 55.07 (6) is amended to read:

ATCP 55.07 (6) DISEASED, OR INJURED, OR ADULTERATED ANIMALS; GENERAL. No person may slaughter a food animal for human consumption, or submit a food animal for slaughter for human consumption, if the person knows or has reason to know that the animal is diseased, or injured, or adulterated. Animals, from producers listed in the USDA Residue Repeat Violator List for use by Livestock Markets and Establishments, are considered adulterated unless the producer provides written evidence of completing, in collaboration with a licensed veterinarian, a

1 course on proper administration of animal medications, approved by the department. This does
2 not prohibit any of the following:

3 (a) A slaughter that is subject to ante mortem and post mortem inspection by the
4 department or the United States department of agriculture.

5 (b) The custom slaughter of an animal injured within 24 hours prior to slaughter,
6 provided the animal is not diseased.

7 (c) The custom slaughter of an animal injured more than 24 hours prior to slaughter if all
8 the following apply:

9 1. The animal is not diseased.

10 2. A licensed practicing veterinarian performs an ante mortem and post mortem
11 inspection on the slaughtered animal.

12 SECTION 2. ATPC 55.07(6)(Note) is created to read:

13 **Note:** The USDA Residue Repeat Violator list may be accessed at the following website:
14 [http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-](http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry)
15 [reports/chemistry/residue-chemistry](http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry) and selecting the link to the USDA Residue Repeat
16 Violator List for Use by Livestock Markets and Establishments.

17
18 SECTION 3. ATPC 55.07(7) (f) is amended to read:

19 ATPC 55.07(7) (f) ~~All drugs administered to the animal as treatments or feed additives~~
20 ~~within 30 days prior to the slaughter submission date, and the last date each drug was~~
21 ~~administered~~ The withdrawal time following administration of all drugs as treatments or feed
22 additives has complied with manufacturer's recommendations.

23 SECTION 4. EFFECTIVE DATE AND INITIAL APPLICABILITY. This rule takes effect on the
24 first day of the month following publication in the Wisconsin administrative register, as provided
25 under s. 227.22(2)(intro.).

Dated this _____ day of _____, 2014.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary

Wisconsin Department of Agriculture, Trade and Consumer Protection

Initial Regulatory Flexibility Analysis

Rule Subject: Drug Residues in Meat and Meat Products
Adm. Code Reference: ATCP 55
Rules Clearinghouse #: Not assigned
DATCP Docket #: 13-R-07

Rule Summary

The proposed rule will specify corrective actions that state-licensed meat establishments must impose on certain livestock producers before the establishment operator accepts animals from the producer for slaughter. The required corrective actions apply to livestock producers who, on two or more occasions during the past year, submit animals testing positive for any illegal drug residue to be slaughtered at state- or federally-inspected meat establishments.

Medications are important for maintaining healthy livestock. However, if not carefully managed, drug residues may remain in animals submitted for slaughter. Residues of medications in meat, particularly antibiotics and anti-inflammatory agents, can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as is needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected, but not required, by the United States Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS) to check the published Residue Repeat Violators List. The list identifies livestock producers whose animals have had two or more positive drug residue test results in the past year. Meat establishment operators are also expected to take appropriate measures before accepting animals from these producers. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture industry is jeopardized by the few Wisconsin producers who repeatedly violate prohibitions against drug residue in livestock and meat products.

Current rules prohibit slaughter of a food animal for human consumption or submission of a food animal for slaughter if the person knows or has reason to know the animal is diseased or injured. The proposed rule will further prohibit someone from slaughtering or submitting for slaughter a food animal for human consumption if they know that the animal is adulterated. The rule then defines animals from producers included on the USDA Residue Repeat Violator List for use by Livestock Markets and Establishments as adulterated unless the producer provides written evidence that they have completed a

course on proper administration of animal medications. The department will approve an acceptable course or courses. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian.

The proposed rule also revises ATCP 55.07, which requires a person who knows or has reason to know that he or she is submitting a diseased or injured animal for slaughter to sign and deliver a written statement to the person who will perform the slaughter. The proposed rule will revise the requirement that the written statement include a list of all drugs administered to the animal as treatments or feed within 30 days prior to the slaughter submission date. The rule will instead require that the statement certify that the withdrawal time following administration of all drugs as treatments or feed additives has complied with the manufacturer's recommendations. This revision acknowledges that some drugs may require a withdrawal time longer than 30 days.

Small Businesses Affected

State-inspected meat establishment operators who accept livestock for slaughter, and livestock producers included on USDA's Residue Repeat Violator list who submit their animals for slaughter at state meat establishments, will be affected by this rule. This proposed rule is anticipated to have very little impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarian. There will be a slight short-term negative economic impact on a small number of livestock producers who are listed on the USDA's Residue Repeat Violator list and, under the proposed rule, would be required to attend a course and improve documentation of their use of animal medications. There will be a slight impact on the veterinarians of these few producers, because completion of the course will require involvement of the veterinarian. To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility taxpayers.

Reporting, Bookkeeping and other Procedures

The proposed rule would require state-licensed meat establishment operators who slaughter livestock to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. The proposed rule would require a producer who is listed on the federal Residue Repeat Violators List to provide written evidence to a meat establishment operator that they have completed a course on proper administration of animal medications before the state-licensed meat establishment may accept animals for slaughter from that producer.

Professional Skills Required

The proposed rule does not require any new professional skills by small businesses. However, livestock producers included on USDA's Residue Repeat Violator list who wish to submit their animals for slaughter at a state-licensed meat establishment will need to complete a course on proper administration of animal medications. Completion of the approved course will require the involvement of the livestock producer's veterinarian.

Accommodation for Small Business

State meat inspection programs only regulate small businesses. State meat inspection programs operate under a cooperative agreement under USDA's authority and must meet federal "at least equal to" requirements. No special accommodation may be made for small businesses to meet the requirements of this proposed rule. However, the rule is expected to have very little impact on meat establishment operators and a slight impact on only a very small number of livestock producers. The rule will affect this small number of livestock producers, but it will benefit small state-inspected meat establishments by further ensuring that the livestock they accept for slaughter are free of drug residues.

Conclusion

Given the potential health risks associated with drug residues in animals for human food, consumers, meat establishment operators, and livestock producers will all benefit from a mandatory procedure for reducing the likelihood that the human food supply contains animals from producers who have been listed for repeated tissue drug-residue violations.

This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

DATCP will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this 21st day of January, 2014.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By Steven C. Ingham
Steven C. Ingham, Administrator,
Division of Food Safety

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

☒ Original ☐ Updated ☐ Corrected

2. Administrative Rule Chapter, Title and Number

ATCP 55-Meat and Meat Food Products

3. Subject

Drug residues in meat and meat products

4. Fund Sources Affected

☒ GPR ☒ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

5. Chapter 20, Stats. Appropriations Affected

102

6. Fiscal Effect of Implementing the Rule

☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget
☐ Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

☐ State's Economy ☒ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☒ Small Businesses (if checked, complete Attachment A)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

☐ Yes ☒ No

9. Policy Problem Addressed by the Rule

The proposed rule will specify corrective actions state-licensed meat establishments must impose on certain livestock producers before the establishment operator accepts animals from the producers for slaughter. The required corrective actions apply to livestock producers who, on two or more occasions during the past year, submit animals testing positive for any illegal drug residue to be slaughtered at state- or federally-inspected meat establishments.

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10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

The rule will have little impact on state inspected meat establishments at which livestock are slaughtered (about 100 establishments), and will have a slight impact on a very small number of livestock producers and veterinarians.

11. Identify the local governmental units that participated in the development of this EIA.

Local governmental units are not impacted by this rule change and did not participate in the development of this EIA.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

State-Inspected Meat Establishments: Current rules prohibit submission for slaughter of a food animal for human consumption if the person submitting the animal knows or has reason to know the animal is diseased or injured. This rule change will further prohibit someone from slaughtering or submitting for slaughter a food animal for human consumption if they know that the animal is adulterated, with animals from producers included on the USDA Residue Repeat Violator List defined as adulterated unless the producer provides written evidence that they have completed a

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

course on the proper administration of animal medications. This rule change is anticipated to have little impact on operators of meat establishment at which livestock are slaughtered, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List.

Livestock Producers: Under the rule change, livestock producers who are listed on the USDA Residue Repeat Violator List will be required to complete a course on the proper administration of animal medications and present written documentation of their course completion before submitting animals for human consumption for slaughter at a state-inspected meat establishment. Very few livestock producers from Wisconsin and neighboring states are on this list and this rule change will have no impact on the majority of livestock producers who follow proper procedures for the administration of animal medications. Livestock producers who take a course in proper administration of animal medications will have to bear costs associated with the course presentation (likely a registration fee to cover expenses incurred by the course presenters) and time away from their regular work. We characterize this impact as slight.

Veterinarians: Successful completion of a course in proper administration of animal medications by a producer will require the involvement of the livestock producer's veterinarian. This involvement will require a time commitment by a very small number of veterinarians. We characterize this impact as slight.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The rule change will benefit state inspected meat establishments, all of whom are small businesses, by clarifying procedures they must follow in the event that a producer on the Repeat Residue Violators List submits a food animal for slaughter. Implementing these mandatory procedures will further decrease the likelihood that animals with illegal drug residues enter the human food chain, and will protect consumer trust in meat from Wisconsin-inspected establishments. The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations. It adds an additional educational corrective action that would be required of the producer by the abattoir operator well before federal regulatory action would normally be taken. The rule change will help livestock producers who are on the USDA Residue Repeat Violators List improve their practices for administering animal medications and avoid future problems. If the rule is not implemented, there is a chance that producers on the Repeat Residue Violators List would present animals containing illegal residues to unknowing meat establishment operators. Although this scenario is unlikely, the economic importance of the meat industry in Wisconsin is high enough that prudent steps should be taken to make illegal drug residues in meat even more unlikely to occur.

14. Long Range Implications of Implementing the Rule

To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, the rule change will have a positive long-term economic impact on Wisconsin's meat industry.

15. Compare With Approaches Being Used by Federal Government

Federal meat and poultry inspection regulations require meat and poultry processors to adopt Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Plants must develop a plan to monitor and document that each key step is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally-inspected plants are required by 9 CFR 417.2 (a) (3) (v) to identify preventive measures for food safety hazards that could arise from drug residues. Drug residues include veterinary drugs, pesticides, and environmental contaminants.

One approach for minimizing drug residue risks is for abattoir operators to avoid accepting animals from sources that have had drug residue violations in the past. Since past performance is often the best indicator as to whether an animal may have a drug residue problem, federal plants are expected, but not required, to consult the federal Residue Repeat Violator List for use by Livestock Markets and Establishments before accepting animals for slaughter. The list is compiled by the National Residue Program (NRP) at FSIS which has collected data on drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12

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months under this sampling program are placed on the federal Residue Repeat Violator List. Federal regulations do not require producers on the list to take any corrective actions prior to submitting animals for slaughter. Federal action against residue repeat violators is generally not taken unless the US Food and Drug Administration investigates, issues a warning letter and, upon further violations, obtains an injunction against the livestock producer. This process is cumbersome, lengthy, and does not happen often.

The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations, and it will enhance the effectiveness of these procedures by adding an additional educational corrective action that would be required of the producer by the abattoir operator well before federal regulatory action is needed.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Michigan currently does not operate a state meat and poultry inspection program and all meat slaughtered and processed in Michigan is federally-inspected by USDA. Illinois' state meat inspection program includes USDA's Federal-State Cooperative program (formerly known as the "Talmadge-Aiken" program). Under this program, state inspectors conduct federal inspections. Minnesota and Iowa operate state meat inspection programs. All processors of meat and meat products, whether operating under state meat-inspection programs or the USDA program, are expected to minimize the risk associated with drug residues and to consult the USDA's Residue Repeat Violator List for use by Livestock Markets and Establishments before purchasing animals for slaughter. The approach proposed in this rule revision is innovative and goes beyond requirements in neighboring states which operate state meat inspection programs. Although enforcement of the provisions in the proposed rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

17. Contact Name

Cindy Klug, Director-Bureau of Meat Safety and Inspection

18. Contact Phone Number

608 224-4729

This document can be made available in alternate formats to individuals with disabilities upon request.

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ATTACHMENT A

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

This proposed rule is anticipated to have little impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. However, meat establishments are already expected to review the list before accepting animals for slaughter. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarian. There will be a slight short-term negative economic impact on a small number of livestock producers listed on the USDA's Residue Repeat Violator list who, under the proposed rule, would be required to attend a course and improve documentation of the use of animal medications. The primary economic impact for these producers would be the registration cost for the course and time away from their farm duties. There will be a slight impact on the veterinarians of these few producers, because completion of the course will require involvement of the veterinarian.

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

To determine the potential impact on small businesses, DATCP requested input from a meat processors professional organization, and the Wisconsin Veterinary Medical Association.

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- ☒ Less Stringent Compliance or Reporting Requirements
☒ Less Stringent Schedules or Deadlines for Compliance or Reporting
☒ Consolidation or Simplification of Reporting Requirements
☒ Establishment of performance standards in lieu of Design or Operational Standards
☒ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

The rule is expected to only have an appreciable impact on meat establishments interacting with the small number of livestock producers on the USDA Residue Repeat Violators List. The rule will affect this small number of livestock producers, but it will benefit small state-inspected meat establishments by further ensuring that the livestock they accept for slaughter is free of drug residues. Under the proposed rule, DATCP must approve the course on proper administration of animal medications that livestock producers on the Repeat Residue Violators List would be required to attend before they can submit animals for slaughter at a state-inspected meat establishment. In evaluating course(s) for approval, the DATCP will carefully balance the effectiveness of the learning activities in the course with the number and duration (and thus economic impact) of these learning activities to ensure that an undue economic burden is not placed on course attendees.

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5. Describe the Rule's Enforcement Provisions

Enforcement of the rule will occur as part of normal meat establishment regulatory activities. Typically, noncompliance with regulatory requirements results in a Noncompliance Report (NR). Upon receiving an NR, the establishment operator takes corrective actions, which are described to the Meat Safety Inspector. In cases of noncompliance related to suspected drug residues, carcasses may be retained for testing. Non-violative carcasses would be released for further processing and/or sale. Violative carcasses would be condemned in accordance with normal procedures.

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6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

☐ Yes ☒ No
